Notice of Allowability	Application No.	Applicant(s)	
	10/003,352	WESTENFELDER, CHRISTOF	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Amendment and Response filed February 4, 2004*.

2. ☒ The allowed claim(s) is/are *1,2 and 5-23*.

3. ☒ The drawings filed on *11/1/01* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

HS
Holly Schnizer

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Heidi Dare on April 13, 2004.

The application has been amended as follows:

1. (amended) A method of ~~preventing ischemic acute renal failure~~ renoprotection in an individual at risk for developing ischemic acute renal failure comprising administering a composition prior to the individual developing ischemic acute renal failure, said composition comprising a therapeutically effective amount of erythropoietin and a pharmaceutically acceptable carrier, for a time and under conditions effective for renoprotection.

2.(amended) A method of treating ischemic acute renal failure in an individual at risk for developing ischemic acute renal failure comprising administering a composition prior to the individual developing ischemic acute renal failure, said composition comprising a therapeutically effective amount of erythropoietin and a pharmaceutically acceptable carrier, for a time and under conditions effective for renoprotection during ischemic acute renal failure.

6. (amended) The method of claim 1 wherein said ~~drug~~ composition further comprises a member selected from the group consisting of pharmaceutically acceptable solvents, diluents, excipients, emulsifiers, and stabilizers.

7. (amended) The method of claim 1 wherein said ~~drug~~ composition is administered systemically.

8. (amended) The method of claim 7 wherein said ~~drug~~ composition is administered at subpolycythemic doses.

9. (amended) The method of claim 8 wherein said subpolycythemic doses are administered 2-4 times over a period of 2-4 days.

11. (amended) The method of claim 8 wherein said doses are in the range of about 250-350 U/kg body weight of ~~EPO~~ erythropoietin in ~~a pharmacological~~ said composition.

13. (amended) The method of claim 1 wherein said composition is administered up to six hours prior to surgery or administration of nephrotoxic agents ~~an ischemic acute renal failure-inducing event~~.

18. (amended) The method of claim 17 wherein said subpolycythemic doses are administered 2-4 times over a period of 2-4 days.

20. (amended) The method of claim 17 wherein said doses are in the range of about 250-350 U/kg body weight of ~~EPO~~ erythropoietin in ~~a pharmacological~~ said composition.

22. (amended) The method of claim 2 wherein said composition is administered up to six hours prior to surgery or administration of nephrotoxic agents ~~an ischemic acute renal failure-inducing event~~.

The following is an examiner's statement of reasons for allowance: The claims are allowable for reasons of record. The prior art of record does not teach or suggest a method of renoprotection or a method of treating ischemic acute renal failure in individuals at risk for developing ischemic acute renal failure comprising administering erythropoietin as is presently claimed and described in the present application (see especially Ex. 5, p. 16 of Specification).

Therefore, Claims 1-2 and 5-23 appear to be in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday, Thursday, and Friday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
April 13, 2004

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SUPERVISORY PATENT EXAMINER
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